

Report on a Survey of the National Residue Program Uniform Application in Cull Cow Plants

Summary

To support the National Residue Program, FSIS Notice 26-99 “Clarification of Cattle Residue Testing Procedures” was issued on August 9, 1999. The purpose of the Notice was to clarify Agency policies regarding when to use rapid, on-site screening tests to facilitate quick decisions on carcass disposition. The Technical Service Center (TSC) conducted a survey to determine if the Notice is being applied uniformly in cull cow establishments. The survey focussed on whether in-plant personnel were following Agency regulations, policies and procedures; inquired if in-plant personnel have the tools they need to complete their residue sampling responsibilities; and assessed the effectiveness of the TSC’s current pathology/residue correlation efforts.

Survey results indicate a need to improve uniformity in following Agency regulations, policies and procedures on the subject of residue testing. VMOs differed in the numbers of screening tests they conduct, the manner in which the tests are conducted, and in the criteria they use to select animals for testing. The survey asked VMOs to identify what they perceive as roadblocks to such testing, and one factor stood out: staffing. Sufficient staffing allows the time to perform expected testing. The survey points to a need for more staff and for making better use of existing inspection personnel in conducting testing. For example, this could be accomplished through a rotating GS-7 Floor Inspector/Residue Aide position, which would also serve the purpose of freeing the VMO to perform more public health-related work.

Two other important factors identified by the survey as barriers to testing are: space in which to perform the tests, and uniform training in how to conduct the tests. During the survey, it was unusual to find an establishment in which there was optimal space provided for storing equipment and supplies and for performing the testing. Most often, equipment was in one location, supplies stored in one or more other locations, and the testing being performed in yet another location. Training was lacking in uniformity in that most of the VMOs interviewed had made use of on-the-job training and self-instructional guides. Less than half had attended a formal, Agency course in residue testing. Such training is important for all inspection personnel working in a slaughter facility, and on-going correlation of the topic is essential for VMOs assigned to establishments that slaughter animals at high risk for residue violations.

The survey found that VMOs who had participated in a TSC pathology/residue correlation course were more likely to follow Agency guidelines regarding residue testing. An intangible result of the survey has been an overall increase in the awareness of residue related issues among Field Operations employees, and the nominations for

attendance at the TSC Correlation sessions has exceeded capacity. A recommendation is to increase the number of correlations, and to include a larger audience, such as circuit supervisors, district personnel, and State inspection program personnel, in order to emphasize the importance of uniform residue testing. In addition, TSC staff have been invited to participate in District meetings to present materials on residues. Members of the data collection teams have become ambassadors for the residue program and have also been involved in sharing information on residues at the District Level.

The survey identified opportunities for improvement in the uniformity of residue testing. The last chapter of this report offers specific recommendations for doing so. The recommendations are categorized by subject matter and are sub-categorized by those that can be implemented by Field Operations and those that should be considered by the Agency as a whole.

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APPENDICES

Project Team List

Data Collection Instruments:

- VMO Survey
- Equipment Checklist
- Supplies Checklist
- FAST Procedure Checklist
- Observation of High Risk Carcass Selection Checklist
- Records Review
- District Managers Survey

FSIS Forms:

- Laboratory Report Form (FSIS Form 10,000-2)
- FAST Worksheet (FSIS Form 6600-7)
- STOP Worksheet (FSIS form 6600-2)
- Noncompliance Record

Plant Awareness Package:
 FSIS Notices 26-99
 Residue Information Sheet

FSIS Notices:
 FSIS Notice 24-00
 FSIS Notice 45-99

Chapter I INTRODUCTION

Background and Purpose

As part of the Food Safety and Inspection Service (FSIS) regulatory oversight of the meat, poultry and egg products industry, the Agency conducts the National Residue Program (NRP)¹. This program tests meat, poultry and egg products for unacceptable (violative) residues from pesticides, animal drugs, or potentially hazardous chemicals. The enforcement/inspector-initiated testing component of the NRP makes extensive use of rapid, on-site screening tests that facilitate quick decisions on carcass disposition.

On August 9, 1999, FSIS issued FSIS Notice 26-99² “Clarification of Cattle Residue Testing Procedures,” to clarify Agency policies regarding when to use such screening tests. In conjunction with the Notice, the Technical Service Center (TSC) Slaughter Operations Staff (SOS) in Omaha, Nebraska, began conducting pathology/residue correlation sessions for veterinary medical officers (VMOs) working in cull cow slaughtering operations. Participants in these correlation sessions have thus far been principally drawn from VMOs assigned to the establishments that slaughter the highest volume of cull cows. So far, three correlation sessions have been held (December 1-3, 1999, May 3-5, 2000, and August 8-10, 2000). The sessions: feature slides of animals and carcasses exhibiting pathological conditions that would cause them to be considered a risk for residue violations; include a wet lab for review of tissue samples from carcasses exhibiting these conditions; emphasize the proper methodology for completing the Fast Antimicrobial Screen Test (FAST); include a discussion of how residue issues relate to HACCP (Hazard Analysis and Critical Control Point) requirements; and address documentation requirements.

The Field Operations (FO) office of FSIS determined a need to assess the uniformity of implementation of the portion of the NRP for which they have most of the responsibility—enforcement/inspector-initiated testing in cull cow plants. To do so, the TSC conducted a survey. The survey inquired if in-plant personnel are following Agency regulations, policies, and procedures; examined whether in-plant personnel have the tools they need to complete their residue sampling responsibilities; and assessed the effectiveness of current pathology/residue correlation efforts by the TSC. This paper presents the results from the survey.

¹ For further information concerning the NRP, we refer the reader to Agency web sites at <http://www.fsis.usda.gov/OPHS/blue99/index.htm> and <http://www.fsis.usda.gov/OPHS/nrp2000/index.htm>

² FSIS Notice 26-99 was reissued as FSIS Notice 24-00 on July 13, 2000, after this project began (both are attached as appendices). All survey instruments refer to FSIS Notice 26-99; therefore, for the sake of consistency, this report will refer only to FSIS Notice 26-99.

Chapter II METHODOLOGY

A variety of data collection methods were employed to address the objectives of this survey and included personal interviews; on-site review of records, supplies, and equipment; and direct observation of procedures relevant to the survey. The data gathering instruments used are included as appendices to this report.

Development of Instruments

A team of TSC representatives, a VMO from a large cull cow plant, and an Office of Public Health and Science (OPHS) representative met in Omaha and developed the survey instruments. The team brainstormed possible questions based on the project purpose, and then re-evaluated the list, selecting the most relevant questions to address the purpose.

Data Collector Training

Four teams of Data Collectors were formed. Each team consisted of a veterinarian assigned to the TSC and a veterinarian assigned to another field location. A list of team members is provided as an appendix to this report. The Slaughter Operations Staff provided the teams technical training similar to the pathology/residue correlations. The training consisted of slides and carcass specimens representative of the conditions outlined in FSIS Notice 26-99, a review and workshop for performing the FAST procedure, and a review of records related to residue testing. In addition, the teams received training in how to use the data gathering instruments. Also in attendance during the training as technical resources were representatives from Office of Policy, Program Development and Evaluation (OPPDE), OPHS, and the National Association of Federal Veterinarians (NAFV), in addition to a VMO from a large cull cow plant³.

Data Collection

The four teams visited 30 establishments, which were randomly selected from the 40 plants that slaughter the highest volume of cull cows in the United States. In the interests of maintaining the confidentiality of the VMOs interviewed, the establishments were assigned alias numbers, which were used throughout the survey. The plants selected represent a variety of operations. The average slaughter rate per day ranged from 120 animals in one establishment to 1,900 animals in another. More than two-thirds of the plants slaughtered less than 1,000 animals per day.

The percentage of animals at high risk⁴ for antibiotic residues slaughtered per day, as reported by the assigned VMOs, ranged from less than one percent to as much as 80

³ The veterinarian involved in the data instrument development and the veterinarian that attended the data collector training were not the same individual.

⁴ High risk animals as defined by FSIS Notice 26-99 are those carcasses that have such pathologies or conditions that make them at risk for residue violations.

percent of the total number of animals slaughtered per day. In 18 of the 30 plants, the percent of high risk animals was 3 percent or less; 8 plants had a 5 to 15 percent rate, and 4 plants had a 30 to 80 percent rate of high risk animals. The average percent of dairy cows⁵ slaughtered ranged from 2 to 99 percent of the total number of animals slaughtered per day. In 18 of the 30 plants, dairy cows accounted for 20 percent or more of the animals slaughtered. (In 13 plants, the figure was 50 percent or higher). Ten of the 30 plants slaughter feedlot culls.⁶ The percent of carcasses retained for veterinary disposition (including those for residue testing) ranged from less than 1 percent to 35 percent. In 19 of the 30 plants, the figure was less than 10 percent, while in 5 of the plants the figure was 20 percent or higher.

The Data Collectors conducted personal interviews with all VMOs available (a total of 34) in each of the 30 plants on the day it was visited. Fifteen of the VMOs were assigned to 11 of the establishments from which a VMO had attended the TSC gross pathology/residue correlations, and 19 VMOs were assigned to 19 of the plants from which a VMO had not attended the correlations. Trips were specifically planned to interview the permanently assigned VMO; nevertheless, included in the total of 34 VMOs are 8 relief VMOs, none of whom have attended the TSC correlations.

The data collector teams also examined inspection records, including FAST Worksheets (FSIS Forms 6600-7), Swab Test on Premises (STOP) Worksheets (FSIS Form 6600-2) in six establishments where FAST was not being conducted, Laboratory Report Forms (FSIS Form 10,000-2), and Noncompliance Records (NRs – FSIS Form 5400-4)⁷. The teams observed FAST/STOP procedures, the equipment and supplies on hand for use in the procedures, and the selection of carcasses deemed to be high risk and candidates for testing.

The teams correlated with the VMOs surveyed as necessary and left Plant Awareness Packets in each establishment they visited. The awareness information included a copy of FSIS Notice 26-99 and a one-page information sheet of commonly needed residue information⁸. Copies of both are included in the appendices to this document.

Interviews were also conducted by phone with the District Managers of districts in which the selected plants were located, and personal interviews were conducted with a variety of personnel assigned to the Midwestern Laboratory in St. Louis, Missouri. Agency data systems were also utilized to collect and review residue data, including MARCIS (Microbiological and Residue Computer Information System), RVIS (Residue Violation Information System), and ADRS (Animal Disease Reporting System).

⁵These type animals traditionally present a high risk for antibiotic residues.

⁶ These type animals also traditionally present a high risk for antibiotic residues.

⁷ Examples of each of these forms are attached as appendices.

⁸ Attached as an appendix.

Report Plan

This report contains five chapters. Chapter I is the introduction to the report. Chapter II describes the methodology used to conduct this survey. Chapter III focuses on whether in-plant personnel have the tools they need to complete their residue sampling responsibilities and discusses how well in-plant personnel are following Agency regulations, policies and procedures. In each section of the chapter, findings are presented and conclusions follow. Chapter IV looks at the effectiveness of current pathology/residue correlation efforts by the TSC. Chapter V presents recommendations for dealing with the issues identified. The recommendations are listed by subject matter, and categorized as those that are applicable to Field Operations as well as broader recommendations for the Agency as a whole.

Chapter III

TOOLS, RESPONSIBILITIES, AND ADHERENCE TO AGENCY STANDARDS.

Data collector teams conducted personal interviews with VMOs; performed on-site review of records, supplies, and equipment; and directly observed procedures to determine if in-plant personnel have the tools they need to complete their residue sampling responsibilities and if they are following Agency regulations, policies, and procedures.

Performing In-Plant Residue Testing

High Risk Carcass Selection

FSIS Notice 26-99 describes the Agency's policy for selection of carcasses for residue testing. All of the 34 VMOs interviewed reported having a copy of FSIS Notice 26-99, and most were familiar with its contents. Although few plants were slaughtering high-risk animals on the day of the visit, Data Collectors discussed carcass selection criteria and observed VMOs selecting animals during ante-mortem and post-mortem examination for residue testing. Data Collectors reported that conversations with VMOs showed that in most plants VMOs were aware of which animals should be tested. Additionally, in most of the plants, the Data Collectors and VMOs were in agreement on what was selected; however, in 2 of the 30 plants, Data Collectors reported they observed carcasses with signs of mastitis, but did not see cows with mastitis being tested. They also noted that in some establishments, VMOs reported not seeing udders because they are being removed in areas of the plant that are relatively inaccessible and dangerous. In the majority of plants, carcasses with signs of pneumonia were selected for testing during the Data Collectors' visit. In five of the 30 plants they were not. The VMO in one of the five plants said he "could not sample all of these types of cases due to time limitations."

In some locations, high-residue-risk condemned animals are the only animals selected for any residue testing. However in other locations, no tests at all are performed on high-residue-risk condemned animals. The most common explanation for this is resource constraints (time and personnel). In some of these cases, the VMO has decided on this approach, and in other cases, supervisory personnel have directed the VMO to take this approach. In most of the plants, downers were being tested as a matter of routine. In three plants, however, not all downers were being selected for testing on the day of the survey visit. In one of these plants, two downers were observed and the supervisor tagged one of the downers for testing. Apparently tags are not in use routinely in this plant, because an establishment employee lost the tag and animal traceback was not in place.

Data Collectors took time during their visits to conduct correlations with in-plant personnel on the contents of FSIS Notice 26-99, and provided specific information when they felt there was a need. Additionally, TSC personnel contacted District Managers and

provided general information on these concerns to ensure policies and procedures are being followed.

Inspection personnel performing on-line post-mortem inspection have the responsibility to identify and retain carcasses that require examination by the VMO. This should include carcasses that are at high risk for residues. No observations were made during this survey relative to carcasses selected by the on-line inspectors. However, we did ask the VMOs whether they were correlating with the on-line inspection personnel. Twenty-three of the 34 VMOs surveyed said they had correlated with inspection personnel on residue-associated gross pathology. Nine of them mentioned correlating on injection sites, two mentioned correlating on FSIS Notice 26-99, and three said they correlated on the type of pathology and criteria for residue sampling.

The survey included a series of questions concerning identification of injection sites. While there are no specific instructions describing the identification of injection sites, these questions were asked to determine what is being done in these establishments. In over 70% of the establishments line inspectors are recognizing injection sites in the neck and rear quarters. However, in only 26% of the establishments are the line inspectors recognizing other frequently used sites for administering antibiotics such as the subcutaneous abdominal vein.

FAST/STOP Testing Procedures

The Data Collectors interviewed VMOs regarding how they conducted in-plant tests, and observed them actually performing in-plant tests. The VMOs surveyed reported that the number of FAST tests performed ranged from less than 1 test per day in one establishment to 250 per day in another. In 9 of the 30 plants, 10 or more tests are performed per day. The time VMOs reported spending on residue testing ranged from 15 minutes in one plant to 12 hours per day in another⁹. Eight of the 34 VMOs estimated they spent less than one hour a day on residue testing, 14 VMOs reporting being in the one to two hour range, and 12 VMOs spent more than two hours.

VMOs were asked what reference they use for performing in-plant residue tests. Most reported using the color version of the FAST guide. The FAST Self-instructional Guide describes Agency procedures for performing the FAST test. The table on the next page shows the answers given.

⁹ The VMO who reported spending 12 hours per day performing residue work was an antemortem veterinarian. This would coincide with his duties, that is, selection of high risk animals to be tested.

Table A: References Used by Survey VMOs for Performing In-plant Residue Tests

<u>Reference</u>	<u>Number of Users</u>
FAST guide (color version)	25
FAST guide (black and white version) ¹⁰	3
FAST video	8
CBT	3
None	6

The most common discrepancies noted by Data Collectors during testing include: swabs left in the kidney less than 30 minutes in six plants; N5 disk placement variations in 17 plants; incubator temperature variations in 9 plants; and improper streaking technique in 4 plants.

Use of Other Resources to Assist With Residue Testing

The survey included a section intended to discern whether VMOs are currently using other resources, either inspectors or plant personnel, to assist with any of the aspects of residue testing. Twenty-six of the VMOs interviewed said they utilized inspection or plant personnel to assist with residue testing. The results from the 26 VMOs utilizing other resources are as follows.

Table B: Other Resources Used by Survey VMOs to Assist with Residue Testing

	<u>VMOs</u>	<u>Inspectors</u>	<u>Plant Personnel</u>
Ante-mortem animals selection	23	2	0
Carcass selection	21	10	1
Sample selection ¹¹	9	12	12
Setting up the test	18	13	0
Reading the test	22	5	0
Security of samples	16	12	0
Dispositions of carcasses	23	0	0

Tracking Procedures

In 29 of the 30 plants, Data Collectors reported that procedures were in place for tracking carcass identification. Most typically this involved placing back tags, ear tags, and other

¹⁰ The original FAST Self-instructional Guide contains color photographs that demonstrate color changes in the test. Some VMOs had been provided photocopies of the original guide. The TSC mailed color-version FAST guides to the VMOs who reported using the black and white version of the FAST guide.

¹¹ Sample selection was clarified during the data collector training to include the actual collection of kidney, liver and muscle tissue from a carcass the VMO has run a residue test on.

ID in bags and attaching the bag to the carcass. All but one plant was meeting the requirements of Part 310.2 of the Code of Federal Regulations (CFR) regarding collecting back tags. Only one plant had a procedure in place for maintaining the identity of carcass type (dairy vs. beef).

Documentation

The Data Collectors looked at inspection records on file in the plants they visited. They randomly selected three Laboratory Report Forms, and three FAST Worksheets (or STOP Worksheets where STOP tests were being performed instead of FAST tests). Noncompliance Records (NRs) were also reviewed and will be discussed in the section titled “HACCP and Residues” on page 18.

A copy of the Laboratory Report Form (FSIS Form 10,000-2) was kept on file in all but one plant (where no such records were available). In 14 of the plants, the forms were not filled out completely. The most frequently mentioned omissions were the project name (4 cases) and the follow-up sample box not checked (5 cases).

FAST/STOP Worksheets (FSIS Forms 6600-7/6600-2) were improperly filled out and/or not complete in 9 of the 30 plants visited. The most frequent omission was backtag/traceback information.

Training

For the VMO to correctly identify animals that are a high risk for residues, it requires knowledge in both pathology and residue testing. All veterinarians receive knowledge in these areas as part of their veterinary training. Additionally, there are several methods by which VMOs receive Agency-specific training in these areas. The inspection personnel assigned to these establishments also need knowledge in pathology and residue testing.

When asked to describe their Agency training on pathology, all the VMOs described more than one method. Their answers are shown in the table below:

Table C: Agency Pathology Training Provided to Survey VMOs

<u>Method</u>	<u>Number of VMOs</u>
On-the-job training	32
Pathology correlations	28
College Station courses	22
Video	16
Computer-based training	16
Correlation with other nearby veterinarians	4

When asked to describe their training on conducting in-plant residue testing, again all VMOs described more than one method. The next table reports their responses.

Table D: In-plant Residue Testing Training Provided to Survey VMOs

<u>Method</u>	<u>Number of VMOs</u>
FAST Self-instructional guide	32
On-the-job training	30
FAST Video training	16
TSC pathology/residue correlation	14
College Station courses	13
Computer-based training (CBT)	8

When asked to describe the training other inspection personnel assigned to the same establishment have received on in-plant residue testing, the most frequent answer (from 16 of the 34 VMOs) was on-the-job training. An additional 4 said other inspection personnel had received no training, and the 14 remaining VMOs either didn't know or didn't answer the question.¹²

Conclusions

Data Collectors evaluated in-plant residue testing performance by looking at high risk carcass selection, testing procedures, documentation of test results and training of in-plant personnel.

Findings indicated that there were discrepancies in selecting carcasses based on FSIS Notice 26-99. Of particular concern was the inconsistency in testing carcasses condemned for certain types of pathology and the failure to recognize signs associated with mastitis.

Inspectors segregate animals, based on pathology, for the VMO to make dispositions. We can conclude that, since inspectors have the ability to recognize pathology, they have the ability to select carcasses for residue testing. However, VMO comments indicate most inspectors are not selecting all high risk carcasses for residue testing. For example, Data Collectors reported that inspectors are detecting injection-site lesions in certain locations, but very few have been provided training to observe for the less obvious locations.

In addition, establishments need to be made aware of things they can do to assist in identifying animals that are a high risk for residues. For example, in 5 of the 30 establishments visited, VMO's reported that plant personnel identify the presence of boluses during rumen harvest and notify inspection personnel. In another establishment in-plant personnel observe for animals with mastitis during ante-mortem to separate them for testing. Establishments should incorporate such activities as part of an effective HACCP program.

The discrepancies noted in testing during the survey are examples of not following Agency procedures and need to be corrected to ensure uniform results of the in-plant

¹² Other inspection personnel were not interviewed during the survey. VMOs were asked to provide this information to the best of their ability.

screening tests. Data Collectors observed that not all VMOs ensured proper saturation of the swab. The FAST procedure guide (as well as the STOP guide) describes the importance of maintaining the swab in the kidney for a minimum of 30 minutes, but not beyond 2 hours. Data Collectors also noted a lack of uniformity in the placement of N5 discs. An N5 disc that is improperly placed may obscure the reading of the zone of inhibition around the swab or a zone around the N5 disc may not be measureable. Wherever Data Collectors noticed such discrepancies, they performed in-plant correlation as appropriate.

The varied use of inspection personnel or plant personnel to conduct residue testing is of particular interest. It has been a long-standing misperception that only the VMO can conduct residue testing. In reality the inspection personnel are an invaluable resource for assisting with this responsibility. Clarification has been provided orally that the only portion of residue testing that must be conducted by the VMO is the reading of the actual test results. Additionally, as we move forward in our understanding of the full incorporation of residues in a HACCP environment, it is likely we will see much more involvement of plant personnel.

A number of inaccuracies in completing forms were found by Data Collectors. Completion of FSIS Form 6600-7 is described in the FAST Self-instructional Guide, and an example of the form is included as an appendix to this report. FSIS Directive 10,210.1, Attachment 1, provides instructions for completing FSIS Form 10,000-2, and FSIS Notice 45-99¹³ includes information regarding completion of both forms. The accurate completion of these forms is essential in that data from these forms is entered into Agency databases. Various reports can be generated from this data. The information on these forms is crucial for the TSC staff to perform proper case follow-up and for the Agency to make valid planning decisions.

VMOs have shown initiative in utilizing a variety of sources for their training needs. However, a large percentage of the veterinarians surveyed have not been provided an opportunity to attend the Agency's formal training courses, which would promote uniformity in the performance of residue testing duties. The lack of formal training opportunities has most likely been due to other priorities taking precedence over training the last several years, which have necessitated the Agency canceling the majority of such courses. Furthermore, it appears that most inspection personnel only receive on-the-job training. Formal Agency training for inspectors (such as the Basic Livestock Slaughter Inspection course) does not provide information concerning residue testing. Additionally, there is no formal correlation program for this audience.

Facilities, Equipment, and Supplies

Facilities

Establishments included in the survey retain carcasses through a combination of retain cages, rail locks, and retain tags; however, it appears that not all VMOs are aware of or

¹³ FSIS Notice 45-99 is attached as an appendix to this report.

are using alternate retention methods. In addition, the majority of Data Collectors reported that it appeared, in most of the establishments visited, that there is insufficient space to rail-out carcasses for veterinary dispositions. It appears that once the area for carcass disposition is full, on-line inspection personnel are not riling out carcasses for residue testing if they do not need to be examined by the veterinarian for a pathology disposition. Data Collectors commented that the VMOs do not slow or stop the line to test these animals because of establishment pressure to allow their slaughter line to run.

In addition, Data Collectors noted in their comments that most VMO's have to be creative in finding space to store supplies and samples, and to perform tests. It was observed in some cases that supplies are stored in one part of an establishment, incubators in another part, and residue tests performed in yet another. In addition, VMOs expressed a concern about actual space for performing tests. One establishment in the survey was an exception in that it has provided a separate room with a desk, freezer, refrigerator, hand washing facility, and locking system for conducting residue testing. Another establishment will soon supply a separate room for inspection personnel to use.

Equipment

Data Collectors looked at incubators and thermometers in all the plants visited. The most commonly used make and model of incubator was the Fisher Scientific 630D (17 plants), followed by the LabLine 100 and 120 (11 plants, of which 4 were doing STOP testing). Two plants were using the Clinical Scientific 100 (one of these plants was doing STOP testing), and one plant was using a CSC 100 (this plant was also doing STOP testing).¹⁴ The incubators varied in age from 6 months old to 20 years old, with 17 of them 5 years old or less¹⁵. In seven of the plants, the age of the incubator was unknown. The incubators were reported to be in good repair in 29 of the 30 plants¹⁶. The incubators were kept in the government office in 24 of the 30 plants, otherwise they were kept in such places as the lab, the break room, or in plant storage. They were reported to be secure in 26 of the 30 plants. At the time the Data Collectors observed the incubators, 15 were within the prescribed temperature range of 44°C., plus or minus .5°C., while 2 incubators were more than 2° outside the range.

A variety of thermometers were reported such as mercury, alcohol, and isoamyl benzoate. VWR Scientific is the most common brand name reported. Six of the thermometers had been calibrated within the past month. It was unknown when the others had been calibrated last. VMOs in two plants reported that since they weren't having any problems, they hadn't seen a need to calibrate.

¹⁴ As a result of this project, the TSC had FAST incubators and FAST Self-instructional Guides delivered to the plants that were doing STOP testing to enable them to perform FAST tests.

¹⁵ FAST was implemented in 1996.

¹⁶ The one incubator found to not be in good repair was immediately replaced.

Supplies

All of the VMOs interviewed said they were consistently able to obtain supplies when they ordered them. If it should happen that they did not have all necessary supplies to conduct residue testing, they said they would borrow supplies from a nearby plant, refrigerate the samples and save them until supplies arrived, or switch to STOP.

In almost all the plants, the majority of necessary supplies were on hand. All had plastic bags, rubber bands, sterile cotton swabs, N5 disks, thumb forceps, and metric measuring devices. A few plants (1 to 3) were lacking one or some of the following: a clean knife, a fine-tipped permanent marker, retain tags, spore suspension, FAST agar plates, and FSIS Forms 6600-7 and 10000-2.

FAST agar plates were outdated in four plants. Although the manufacturer's date on the spores varied, none of the Data Collectors reported turbidity in the spore vial that would have been an indicator for loss of effectiveness. Eleven of the 30 plants were using automatic dispensers for N5 disks. The rest used a variety of manual dispensers. Five of the plants were not properly storing their N5 discs. In four plants, N5 discs were not refrigerated, and in a fifth plant N5 discs were refrigerated but not in bags with desiccant.

Conclusions

Data Collectors concluded that in some plants, once the VMO's retain rail was full, then carcasses that should be selected for residues testing were not being railed out. FSIS regulations require an establishment to present carcasses at a speed in which a proper disposition can be made. Residue testing of those animals that are considered to be a high risk for residues is part of this disposition. It would appear that this situation may be a significant roadblock for our inspection personnel to adequately test carcasses moving through cull cow plants.

Data Collectors noted during this survey that a number of establishments have limited space for performing residue testing and for storing supplies and equipment associated with such testing.

There is a variety of equipment type and age in the field. For the most part it was found to be in good repair, and was immediately replaced where not in good repair. The manufacturer of the most common type of thermometer was contacted concerning calibration of the thermometers. The thermometers are received calibrated and should remain accurate for some time. The manufacturer does not include information on calibration. It has been previously recommended that the electronic monitoring device, TEMPTale, be used for monitoring and validation of plant incubators.

It appears that obtaining and maintaining supplies is feasible in the in-plant environment. VMO's in some cases were not properly storing their supplies. Also, the lack of automatic dispensers at many locations may have led to the variability in disc placement. The laboratory is re-supplying automatic dispensers.

HACCP and Residues

Hazard Analysis and HACCP Plans

To better assess whether FSIS in-plant personnel are following Agency policies and procedures, some general questions were asked to better understand how establishments are currently addressing residues in a HACCP environment. The VMOs reported that residues were included in the hazard analyses of 14 of the 30 establishments visited. Of those 14 plants, 9 included residues in their HACCP plan. Four of the establishments visited perform their own residue testing. One tests downers, one tests the same animals as tested by FSIS, one does STOP testing on bulls as part of their process to certify natural organic beef, and one tests animals slaughtered as a requirement for a specific customer.

Documentation

Data Collectors were asked to look at Noncompliance Records (NRs) written for residue violations in each of the establishments visited. They reported confusion among VMOs about the circumstances under which NRs should be written for residue violations. Some inspectors are writing NRs for positive sample results even though residues are included in a plant's HACCP plan and the establishment is following their plan. Other inspectors are not writing NRs even though residues have not been included in the plant's HACCP plan and a number of positives from the same producer have been reported, or even though cases have been made. In examining the NRs, the Data Collectors described several as having an incomplete description of the noncompliance, or lacking a plant response, or lacking satisfactory corrective action. For example, the HACCP plan was not reassessed as is required by §417.3(b), and/or no tracking system for repeat violators had been developed, which is one way to address 417.3(a)(3).

NRs were on file in 15 of the plants visited. Of the 34 total NRs examined, 24 had been assigned a procedure code of 03J01 and 5 were assigned a code of 03J02. The remaining five NRs, written in two plants, had been assigned a procedure code of 05C01, which should not be used for a residue sampling violation.

- Of the NRs with a procedure code of 03J01, 8 had monitoring as the trend indicator, 11 had verification, 4 had corrective action, and 1 had no trend indicator listed.
- Three of those with a procedure code of 03J02 had monitoring as the trend indicator, one had verification as the trend indicator, and one had no trend indicator listed.
- None of those with a procedure code of 05C01 had a trend indicator listed.

While there was a lot of variation in addressing residues as part of HACCP, out of the 30 establishments visited, it was reported by the VMOs that 28 of the establishments are cooperative in providing traceback information.

Conclusions

The findings related to residues and HACCP are consistent with anecdotal information that suggests that there is a need for improvement in hazard analysis and HACCP plans. The HACCP regulations require all establishments to conduct a hazard analysis and to consider all of the potential hazards in their operations. The regulations include chemical residues as a specific hazard to be considered. While it would not be expected that all establishments that slaughter cull cows consider antibiotic residues likely to occur in their operations and therefore include a CCP, it would be expected that all of these type operations consider antibiotic residues in their hazard analysis.

FSIS Directive 5400.5 is the primary place that Agency policy is described concerning documentation of NR's. There are no specific instructions concerning the documentation of NR's for residue violations. Field Operations had provided some guidelines to District Offices in April 1999, suggesting that violative drug residues in an establishment with no CCP for residues should be documented using the 03J01/02 procedure codes and the verification trend indicator.

Roadblocks to Residue Testing

Perceived Barriers

VMOs were asked about their perceptions of potential barriers that interfered with their performance of residue testing. The most frequently mentioned were staffing, task interference, frustration with the program, and prioritization of tasks. It can be inferred from their comments that these barriers are interconnected. Foremost among the perceived barriers mentioned was staffing. Twenty of the 34 VMOs said staffing was a barrier at least sometimes. At the time of the visit, 15 of the 30 plants were not fully staffed. Some were short of VMOs, but most were short of inspectors. In two cases, intermittents were reported to be filling in. In the 15 plants that were fully staffed, it was noted that at times personnel were being pulled to staff other assignments in the vicinity that were short staffed.

The table on the next page depicts how VMOs answered the question "Do any of the following barriers interfere with your performance of residue testing?"¹⁷

¹⁷ Based on the question, we are not able to determine if the barriers and frustrations are exclusive to the inspector-initiated sampling, or if they represent the barriers and frustrations associated with the entire NRP.

Table E: Barriers Perceived by Survey VMOs to Interfere with Performance of Residue Testing

<u>Perceived Barrier</u>	<u>Percent who Responded Yes or Sometimes</u>
Staffing	65
Task interference (other duties)	61
Frustration with the program*	48
Prioritization of tasks	47
Inadequate space	26
Don't know how to use electronic NRs	24
Environmental effects on the test	24
Supplies out of date	21
Documenting NRs	18
Supplies not available	15
Unable to secure supplies	15
Equipment not available	15
Supplies not in useable condition	12
Unable to secure retained carcasses	12
VMO training not adequate	9
Inspector training not adequate	9
Rotation	9
Equipment not functioning	9

*The VMOs were asked to elaborate on their frustration with the residue testing program. The table below illustrates their responses.

Table F: Frustrations Identified by Survey VMOs

<u>Frustration</u>	<u>Percent who Responded Yes or Sometimes</u>
FDA does not effectively prosecute violators	73
Too much work	59
Lab is slow	38
Communication in general	34
Lack of communication on follow-up cases	32
High volume of high risk animals	31
Never know what happens after the test	21
Carcasses condemned for other reasons	14
Lack of cooperation from establishment (misinformation or lack of information about producers)	10
Repercussions/threats/harassment by establishment	3
Lack of support from supervisors	3

Additional frustrations mentioned in passing by VMOs included problems using computers and lack of communication between the district office, state inspection officials, and in-plant inspection officials about residue violations.

Strategies for Dealing with Problems

When asked “What is your strategy for dealing with days you have a large volume of residue samples?” most (24 of the 34 VMOs) said they ensure all testing is accomplished. Some (10 of the 34) delegate responsibility to inspection personnel, some (6) store the samples for later, and some (6) run a small number of tests.

Seventeen of the 34 VMOs reported they had experienced no problems with the FAST test not working as expected, while 8 VMOs identified incubator problems and 8 VMOs reported growth problems. When asked what they do if they have invalid test results for the day, all but one said they would retest. The other one said “forget it and move on.” While these VMOs reported incubator and growth problems, these findings were not substantiated during the observation portion of the survey.

Conclusions

The majority of VMOs felt that there were at least some barriers to following Agency regulations, policies and procedures for residue testing. In order to ensure uniform application of residue testing these barriers, whether real or perceived, must be addressed and the Agency must ensure that these perceptions do not interfere with the residue testing being conducted.

It is recognized that the VMO’s assigned to these establishments have many tasks that they must prioritize. In addition to prioritizing food safety procedures (e.g., HACCP, SSOP, pathology dispositions, residue testing, *Salmonella* testing) and procedures addressing other consumer protection (e.g., carcass AQL, offal checks), VMOs are responsible for supervision of food inspectors, and maintaining staffing of the slaughter line. As part of the survey, VMO’s were asked how they would prioritize certain tasks. The VMOs surveyed easily ranked food safety procedures as more important than other consumer protection activities. It appears that VMOs have more difficulty in prioritizing activities such as inspector breaks and how that compares to food safety work, based on the need to conduct certain administrative duties.

When the VMO’s interviewed as part of this survey were asked what recommendations they had for improving residue testing in the plants to which they are assigned, 11 of the 34 VMO’s said more staffing was needed in order to accomplish all the testing called for. Some suggested assigning an additional VMO, and some suggested creating a GS8 position for residue testing in plants with high pathology. Four of the VMO’s felt that restrictions should be placed on repeat violators. Other suggestions included more training for all personnel involved, more space to perform testing, bigger retain cages, and bigger refrigerators.

District Office Perspective

The District Managers were interviewed for the 10 Districts in which the survey plants were located (Alameda, Atlanta, Boulder, Dallas, Des Moines, Madison, Minneapolis, Philadelphia, Raleigh, and Salem). All reported that they see their role in the residue program as ensuring proper flow of information from TSC to field inspectors, providing assistance in tracebacks, providing information related to open case followup, and providing information to producers and establishments related to incoming animals for follow-up testing. The manner in which and by whom these services are provided, however, varies considerably from district to district, depending on the resources available to them.

District Managers had a number of suggestions for improving the uniform application of the National Residue Program, and included the following:

- Change the wording of the Notice to eliminate gray areas such as “may.” Instead use “should” and “must.”
- Clarify everyone’s role in residues, including where residues fit into overall priorities and how to handle residue violators.
- Ensure District Managers are kept “in the loop.”
- Help Districts deal with residue cases, repeat violators, and plants.
- Supply read-only access to RVIS down to the IIC level.
- Separate out the open case list by region, highlighting repeat violators.
- Correct the test results on HPDesk, which are showing wrong tolerances and therefore cannot be trusted.
- Push residues into the HACCP arena. Ante mortem and post mortem examinations do not fit in with HACCP. Plant should be doing testing.
- Put responsibility with the plant instead of the grower, because only FDA can deal with the growers.
- Place focus on the haulers and producers.
- Have IIC’s train inspectors on what they want railed out.
- Relieve the VMO from administrative duties.
- Provide more staff for physiological and toxicological issues. Current recruitment efforts are not doing the job, and human resources issues due to attrition will be huge over the next two years.
- Test animals that are condemned.
- Provide more timely results from the lab.

Conclusion

In summary, the District Offices have a crucial role in the implementation of the NRP. Most felt they could benefit from a better understanding of their exact role, particularly since there is no specific dedicated resource within the District Offices to handle residues. The District Managers offered many valuable suggestions, many of which coincide with those resulting from this survey.

Laboratory Visit

Staff from the TSC visited the Midwestern Laboratory during this project. The majority of information gained and recommendations resulting from this visit are outside the context of this report¹⁸. However, it was evident that the laboratory is currently running at its full capacity. The staff reported that the laboratory demonstrated some examples of mislabeled and incorrectly prepared and packaged samples and the delays that can result from such errors in sample submission.

Conclusion

In summary, the Midwestern laboratory is an essential component of the NRP. While many suggestions and ideas resulted from visiting with the staff, the majority of them are outside this project. There is concern that the laboratory is running at its full capacity at the present time.

¹⁸ See general recommendations in the recommendation section.

Chapter IV

EFFECTIVENESS OF CURRENT TSC PATHOLOGY/RESIDUE CORRELATION EFFORTS

This chapter provides graphical representation of the effectiveness of the correlation training provided by the TSC to field VMO personnel and to determine if the intent of FSIS Notice 26-99 is being followed.

Chart 1 – VMOs Correlating Residue Information with In Plant Personnel depicts that 60% of the establishments visited (correlated and uncorrelated) during this study are making pathology/residue correlation materials available to in plant personnel.

Chart 2—Establishments Not Selecting FSIS Notice 26-99 Conditions demonstrates nearly two thirds of the establishments visited have not been correlated. However, VMO personnel assigned to those establishments are selecting animals that fit the criteria of FSIS Notice 26-99 at approximately the same rate as the correlated facilities.

Chart 3—FAST Test—Average Swab Time in Tissue—Correlated Establishments clearly shows 80% of the correlated plants visited are properly maintaining the minimum time a swab should be left in tested tissue.

Chart 4—FAST Test—Average Swab Time in Tissue—Uncorrelated Establishments reinforces the need for structured pathology correlation because of the wide variation observed in the time a swab was left in tested tissue.

Chart 5—FAST Test—Minimum/Maximum Incubation of Plates—Correlated Establishments reflects that of those establishments that Data Collectors recorded a minimum incubation time, all correlated establishments met the minimum (6 hours) and maximum (18 hours) standards.

Chart 6—FAST Test—Minimum/Maximum Incubation of Plates—Uncorrelated Establishments displays a wider variation of plate incubation. 36% (5) of the uncorrelated establishments did not provide maximum incubation times.

CHART 1--VMOs Correlating Residue Information with In Plant Personnel

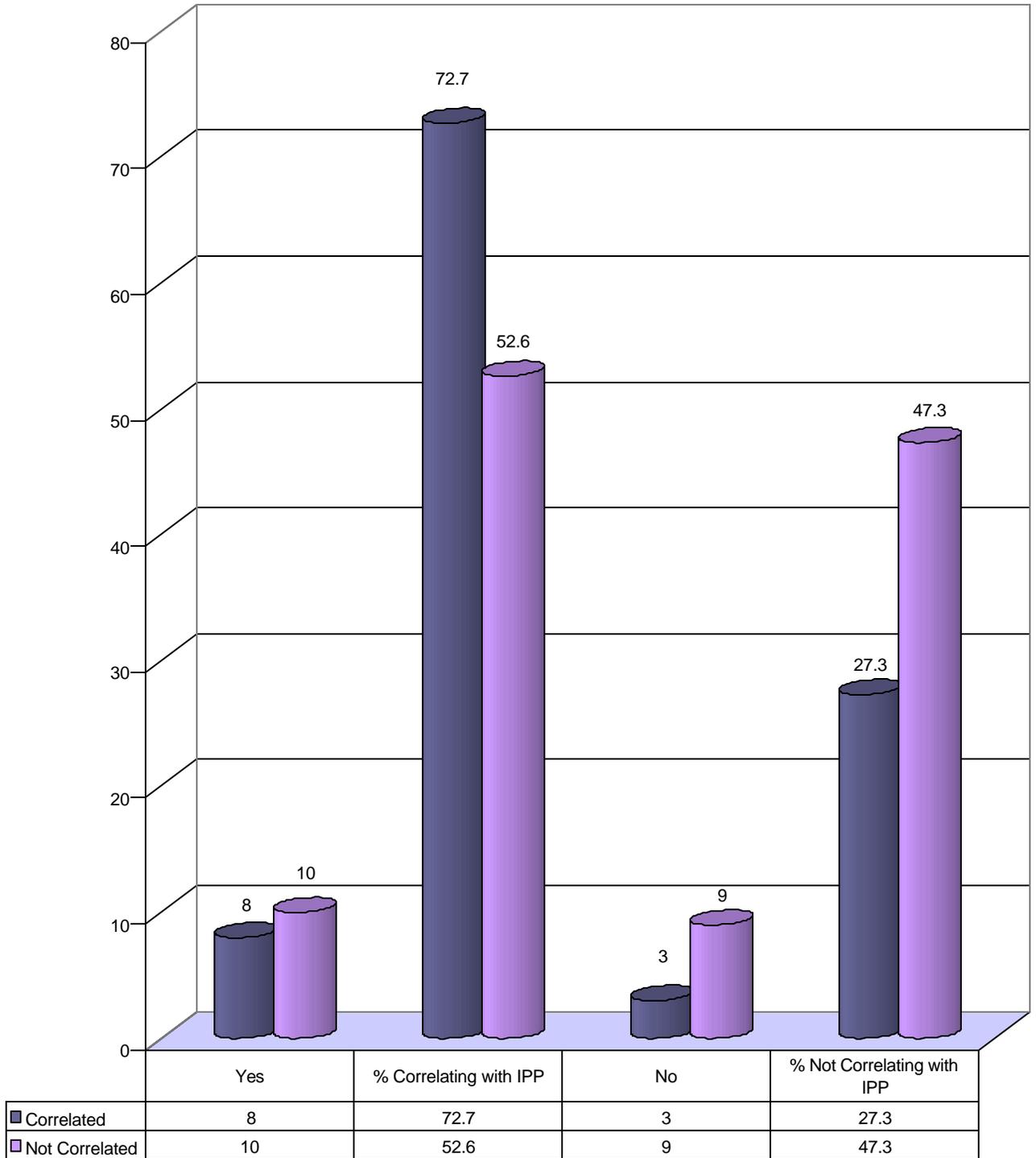
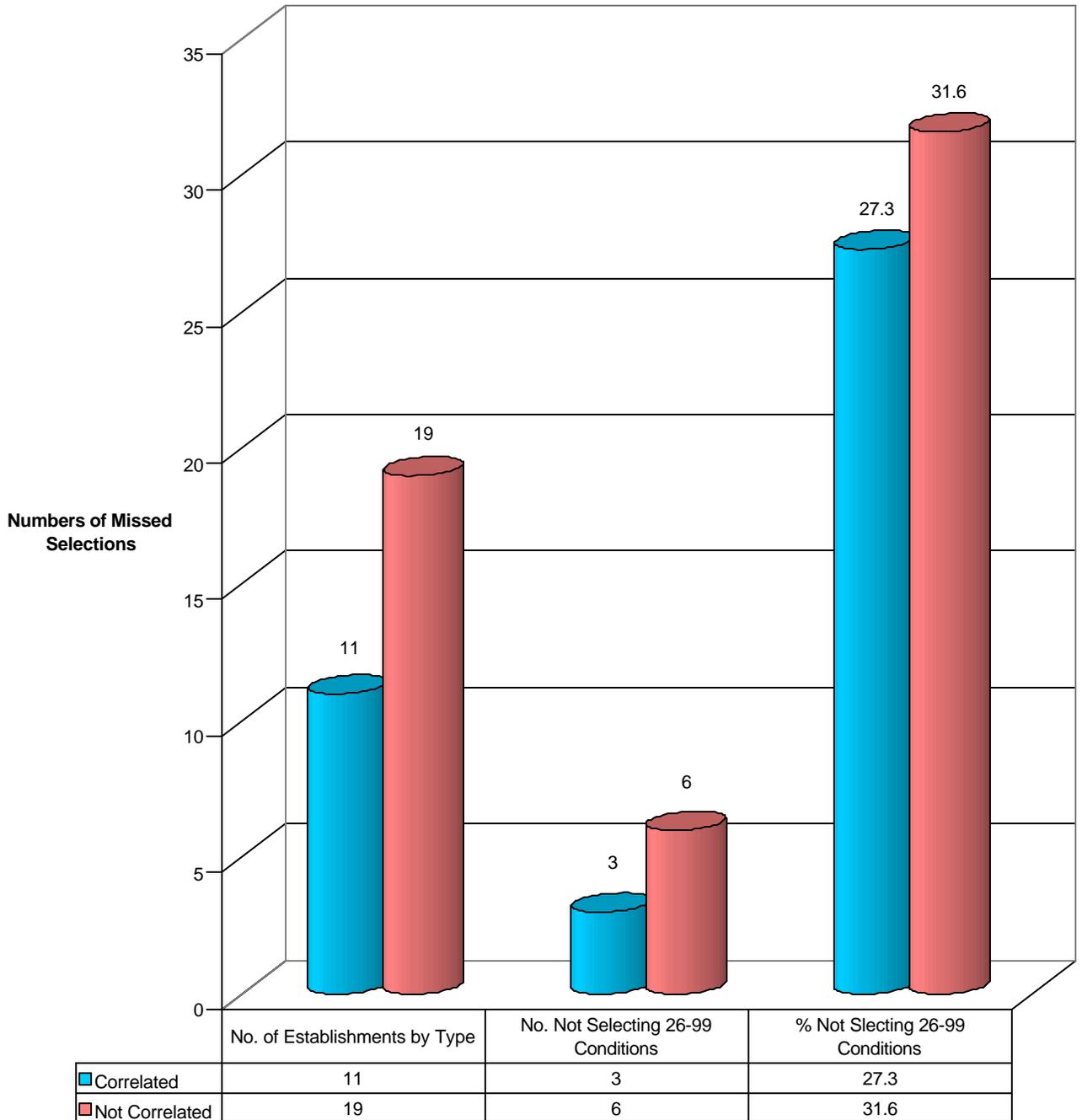


CHART 2--Establishments Not Selecting FSIS Notice 26-99 Conditions



Type and Number of Establishments

CHART 3--FAST Test--Average Swab Time in Tissue--Correlated Establishments

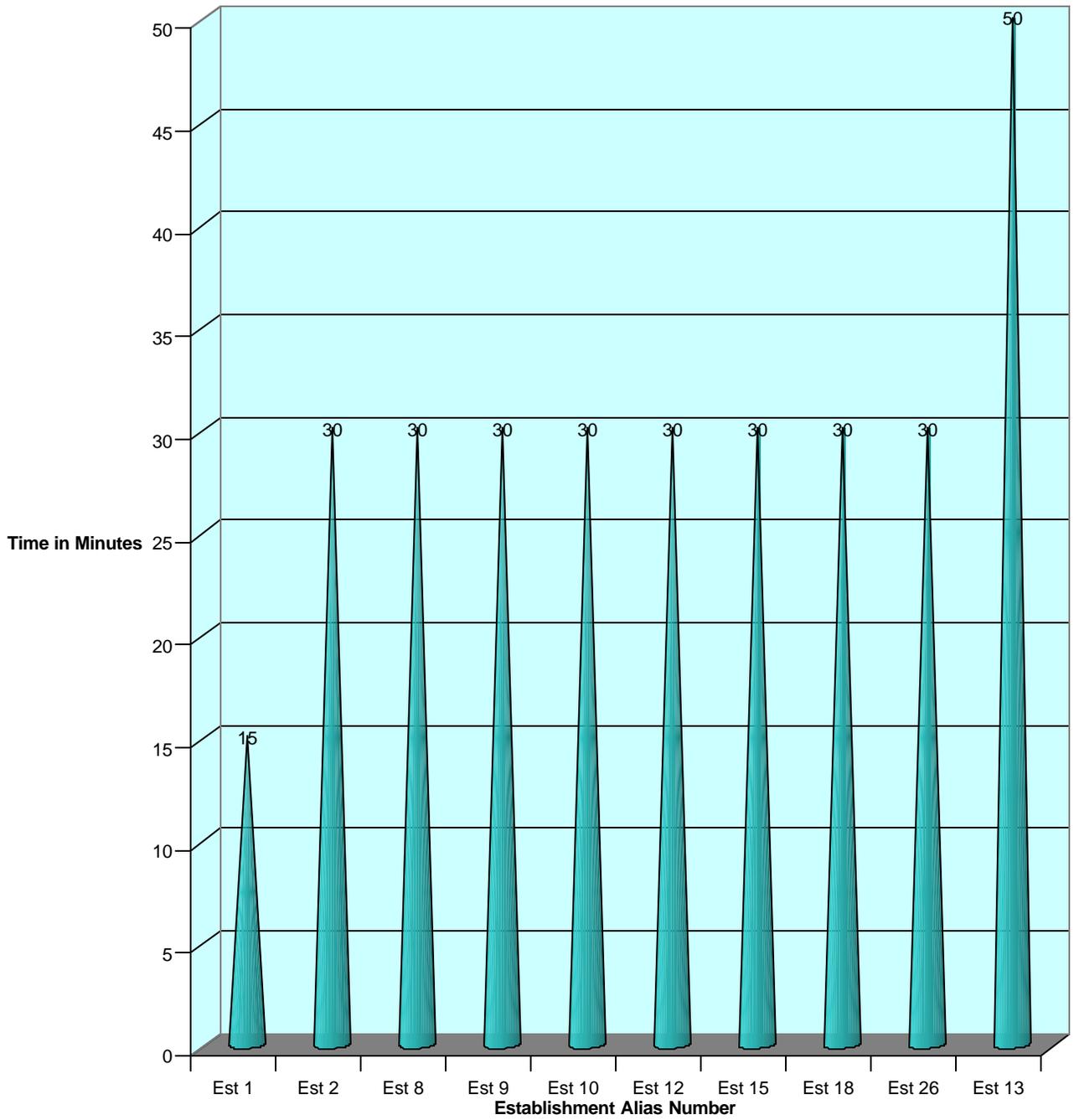
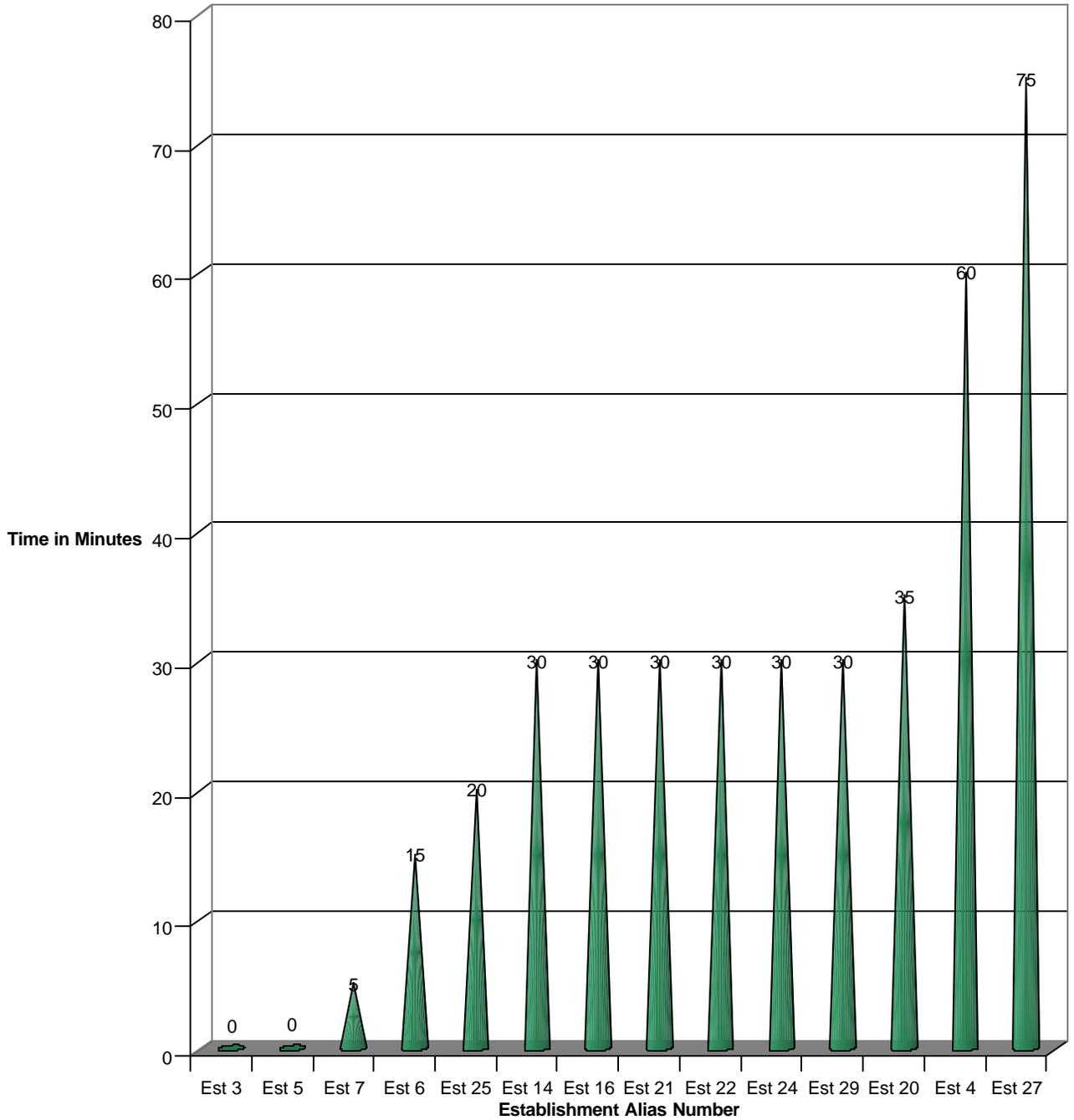
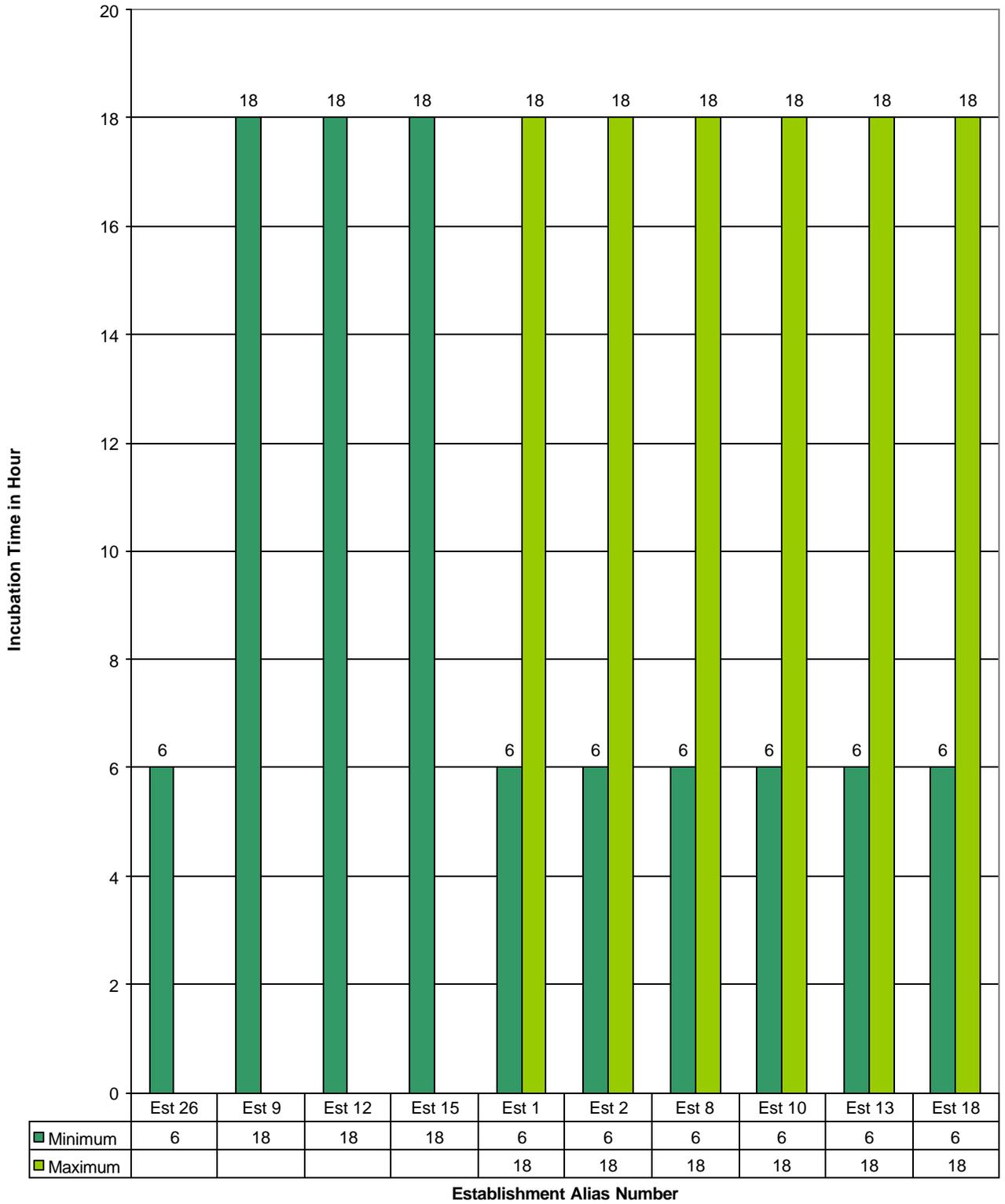


CHART 4--FAST Test--Average Swab Time in Tissue--Uncorrelated Establishments



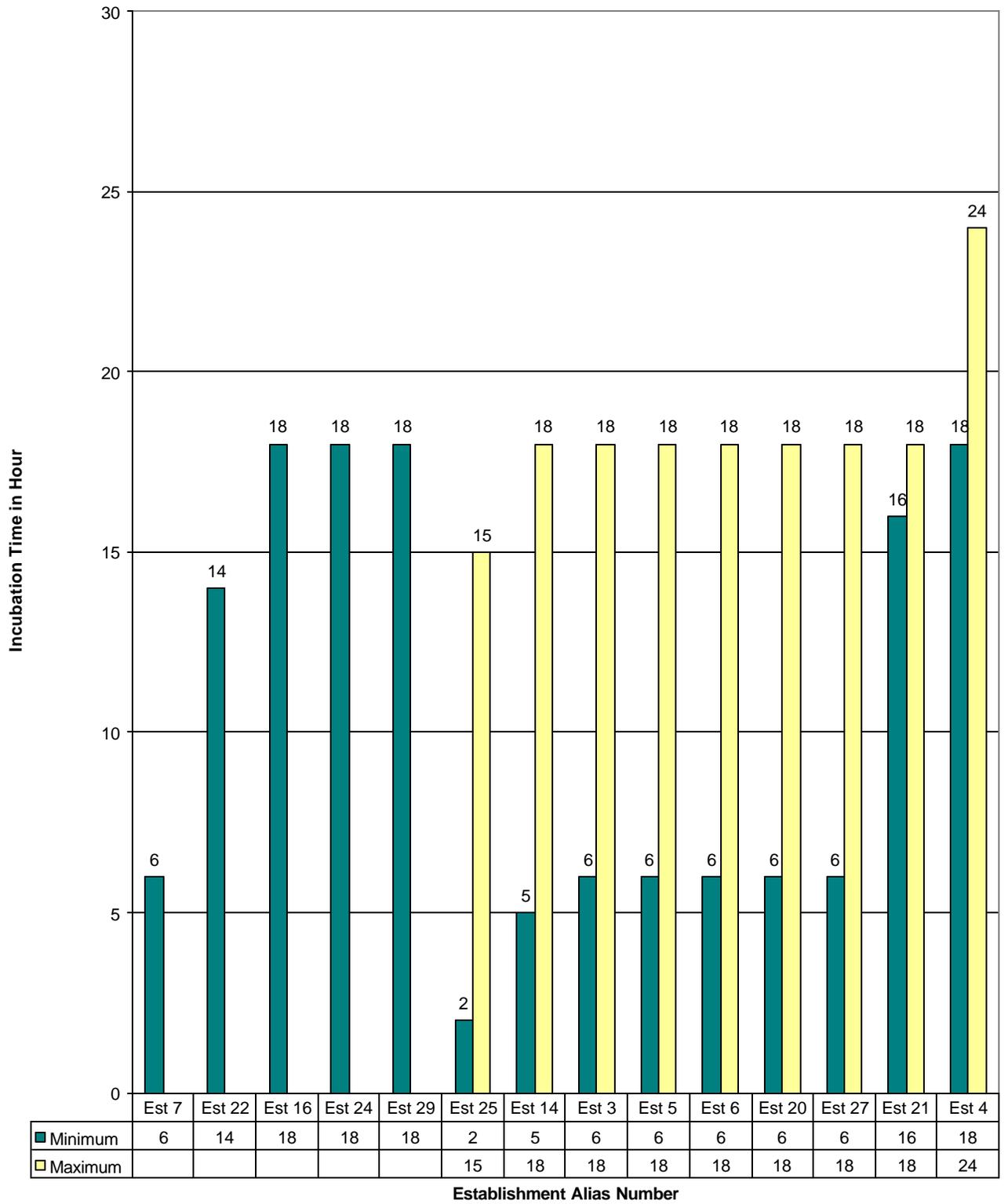
No Response from Est 3 and 5

CHART 5--FAST Test--Minimum/Maximum Incubation of Plates--Correlated Establishments



Est 9, 12, 15, and 26 did not provide a maximum incubation time.

CHART 6--FAST Test--Minimum/Maximum Incubation of Plates--Uncorrelated Establishments



Est 7, 16, 22, 24, and 29 did not provide a maximum incubation time.

As part of the TSC pathology/residue correlation training sessions for VMOs, the importance of residue testing is stressed and fully described. Tables G (below) and H (on the next page) demonstrate that, overall, residue testing of carcasses has increased, when comparing FY1999 data to FY2000 data. The tables also indicate that correlated establishments have a greater increase in numbers tested compared to uncorrelated establishments. Correlated establishments increased 2.3 times versus 1.49 times in uncorrelated establishments. This finding suggests that correlations have had an impact on residue testing.

Table G: Comparison of Residue Tests Performed in Correlated Establishments FY 99 vs 00

Establishment	<u>*Correlated Establishments</u>			
	FY99 Slaughtered	FY99 Tested	FY00 Slaughtered	FY00 Tested
Est 29	420,499	80	304,863	1,759
Est 26	466,949	9,347	304,092	19,224
Est 18	343,935		213,037	48
Est 8	336,402	135	230,029	61
Est 4	320,384	119	312,405	2,407
Est 2	258,174		275,721	806
Est 13	222,210	31	159,143	78
Est 10	218,118	147	148,046	434
Est 15	209,098	58	164,970	153
Est 1	202,238	182	129,958	618
Est 3	135,187	1,785	80,836	4,560
Est 5	126,706	9	79,152	5
Est 9	97,797		171,764	201
Est 12	82,319	1,428	56,318	1,286
Est 19	60,159	896	40,606	999
TOTALS	3,500,175	14,217	2,670,940	32,639

* For this table, correlated establishments are those establishments at which an assigned VMO has been correlated (whether or not this was the person interviewed in the survey).

Table H: Comparison of Residue Tests Performed in Uncorrelated Establishments FY 99 vs 00

<u><i>Uncorrelated Establishments</i></u>				
Establishment	FY99 Slaughtered	FY99 Tested	FY00 Slaughtered	FY00 Tested
Est 6	294,119	169	214,140	435
Est 20	174,241	52	40,686	856
Est 16	158,400	306	70,497	102
Est 24	114,344	1,841	108,138	1,566
Est 28	98,861	56	67,533	52
Est 27	97,952	40	67,866	48
Est 21	86,224	131	69,229	136
Est 30	85,050	4	59,643	
Est 25	71,778	217	34,726	593
Est 14	50,309	402	41,686	856
Est 7	47,931	75	30,643	56
Est 23	42,499	241	30,639	585
Est 11	41,199	6	50,294	591
Est 17	40,026	526	32,144	514
Est 22	34,029	454	33,138	326
TOTALS	1,436,962	4,520	951,002	6,716

Chapter V

CONCLUSIONS AND RECOMMENDATIONS

Conclusions:

The survey was conducted in 30 of the top 40 establishments slaughtering cull cows, and it is anticipated that the data could be inferred to represent all of the top 40 establishments. What we are not able to predict is the applicability of this information to the smaller establishments. Additionally, two of the establishments visited were Talmadge-Aiken (T/A) facilities. Because these two establishments ranked at opposite ends of the spectrum as far as following Agency regulations, policies and procedures, no conclusion can be drawn about this population. Some specific recommendations are included, however, to ensure consistency in these establishments as well as state-inspected facilities.

The survey demonstrates there is some improvement in application of Agency regulations, policies and procedures in those establishments in which the IIC has been correlated. This was particularly evident in the portion of the survey addressing the knowledge related to the selection of carcasses and the actual performance of the FAST test.

The survey identified that most inspection personnel had the tools (with the exception of labor and space) to conduct their testing. One incubator was found non-functional and was immediately replaced during the survey. Another concern heard at some frequency that needs to be addressed was that there is inadequate space on the slaughter floor for retention of carcasses for veterinary disposition.

There are many facets to the residue picture at this time. The Agency (OPPDE) is working to publish a Federal Register Notice and conduct a public meeting regarding the impact of full HACCP implementation on the residue program. The industry recently conducted a Cull Cow Working Group to address residue issues amongst themselves. One result of their meeting was a letter to the Agency requesting that the Agency develop a cooperative program with FDA whereby a listing of "repeat violators" is updated by FDA and made public by FSIS, naming suppliers with more than one violation in a 12 month period. They are requesting written notification of violations by FSIS to continue with a supplemental letter from the packer to the vendor notifying them that their animals will not be accepted unless subject to inspection/testing by the packer. Another major Agency residue initiative includes consideration of publishing a target tissue policy. All of these initiatives may have an impact, direct or indirect, on the implementation of Agency regulations, policies and procedures.

The findings from this survey that indicate the need to improve the uniformity of application of Agency regulations, policies and procedures primarily are the result of the barriers described in Chapter III. The survey demonstrated that the pathology/residue correlations are one tool that the Agency has been utilizing to address concerns related to understanding Agency policies and procedures.

Recommendations:

The findings from this survey that indicate the need to improve the uniformity of application of Agency regulations, policies and procedures appear to be the result of the many barriers identified during the project. The survey demonstrated that the pathology/residue correlations are one tool that the Agency has been utilizing to address concerns related to understanding and uniformly following Agency policies and procedures.

The following recommendations are intended to provide ideas that, based on the survey, will eliminate or minimize the barriers to application. Also, the recommendations are intended to be both “doable” and specific to address the concerns raised by this survey. They are presented by topic of major barrier identified and are further broken down to indicate those that could be implemented by Field Operations as well as those that should be considered by the Agency. It is anticipated that once any barriers are eliminated or minimized, Field Operations managers can address outliers through accountability.

Please note: while all the following recommendations are considered important, a diamond-shaped symbol was utilized to denote those considered most important.

General

- ❖ Conduct an Agency "Residue Summit" to include senior managers from all three Agency program areas. The Agency reorganization resulted in major infrastructure changes. Now that the reorganization has been in place for some amount of time, the Agency could assess the effectiveness of the current structure for implementing the NRP. The "Summit" could address roles and responsibilities and ensure the most effective and efficient process for work is being utilized. This meeting could ensure no duplication of work and could consider all ideas for improvement. The meeting could consider such concerns as electronic transmission of laboratory results, at what level carcass dispositions should be made, etc.
- ❖ Circuit supervisors could be encouraged to compare the findings from this survey and make an assessment of the smaller establishments in their assignments. The TSC could collect information from the circuit supervisors and make recommendations based on their findings. In addition, this group does recommend that a follow-up study be conducted once recommendations have been implemented to ascertain their effectiveness and suggest any appropriate modifications. This could be accomplished through mail surveys and/or follow-up visits.

Staffing

Staffing was considered by the VMOs surveyed as the greatest barrier to uniform application of the NRP. It is also one of the more difficult areas in which to provide easy recommendations to address the concerns. Technological advances in the industry have

led to a significant relocation and concentration of certain high volume/pathology slaughter activities in specific areas of the country. Our Agency continues to utilize a work measurement system designed for a 1960's vintage industry. A "typical plant" is not what it used to be and the old parameters do not apply. Additionally, there were some of the establishments visited that were fully staffed and, in this situation, inspection personnel were often borrowed to fill assignments at other establishments with a greater need.

Suggested recommendations for FO include:

- ❖ Re-structure/re-prioritize VMO assignments and allow more time for food safety work including residues.
 - Use supervisory food inspectors for supervision of food inspectors and administrative functions
 - Use a combination of VMO/CSO to fill some dedicated positions (not assigned to a specific plant) to conduct broader food safety responsibilities (e.g., HACCP plan design, residue work) at multiple establishments in a geographical area.
 - To accommodate for additional staffing needs, utilize an additional GS-7 position to accomplish residue work. The rotating GS-7 Floor Inspector/Residue Aid position gives line inspectors a stake in the process and they become more result-oriented.

- ❖ Clarify the role inspection personnel can take today.
 - FSIS needs to eliminate local personnel paradigms that require that all tasks associated with in-plant residue testing, including plate and sample preparation, be performed only by a veterinarian.
 - Issue an FSIS Notice to describe roles that can be accomplished by other inspection personnel.
- Continue all efforts to fill vacant positions, particularly in these operations.
- Supervisors need to understand the demands of a high volume/pathology slaughter establishment and do what they can to provide adequate staffing and other support.
- Staff should not be borrowed from the high volume/pathology establishments.

Suggested Agency recommendations include:

- Update career ladder
 - Career ladders for veterinarians should be based on the technical demands of a position as determined by its food safety and public health challenges. There are many potential public health responsibilities in high volume/pathology slaughter plants yet these assignments are currently filled with the lowest graded veterinarians based on current staffing criteria.

Training and Correlation

Training was another area recognized in the survey that offers many opportunities for improvement. Training on identification of pathology and conditions that lead to the highest risk for residues is important for all inspection personnel working in a slaughter

facility. Ongoing correlation on this topic is essential for the VMOs assigned to the high risk establishments.

Suggested FO recommendations include:

- ❖ Incorporate residues into the Basic Livestock Slaughter Inspection Course.
- ❖ Dedicate additional time to residues in the VMO Livestock Slaughter training course.
- ❖ Review all training materials related to residues and ensure they emphasize current Agency policy.
- ❖ Develop resource material for VMOs to utilize in training/correlating their on-line slaughter inspection personnel.
- ❖ For on-going VMO correlation—have a site on the TSC home page for “residue correlation”. Have a select few VMOs provide digital photos, lab results, and case history. The TSC could create the “Cases of the Month”. They could have a few cases each month and provide the history and photographs. Have questions for the person working through the case, such as—acute or chronic? Would you test? Then provide lab results to help them better understand acute vs. chronic. Also provide FAST and any follow-up residue information.
- ❖ Work with FDA-CVM to produce a video and/or CBT that clearly explains FDA roles and responsibilities for case follow-up. Include this as part of the correlations and HRDS training. Ensure that there is a better understanding of what is done by FDA on the cases reported.
- ❖ Customize the pathology/residue correlation for a Circuit Supervisor audience and ensure all CSs (VMO and non-VMO) attend, and then hold them accountable for ensuring uniform application.
- ❖ Provide in-plant correlation to as many cow cull plants as possible.
- ❖ T/A Plants: request participation at February State Directors’ meeting and present information on Agency expectations for the selection of high risk carcasses—have high level FSIS management stress this is the expected standard to be considered equal to.
- ❖ T/A Plants: invite attendance at correlations (started for October session) - consider customizing the correlation for this audience.
- Provide a digital camera to each DO. Have the camera available for the VMOs in these establishments to do on-line correlation on specific cases with TSC.
- Ensure training materials address signs associated with mastitis such as ventral inflammatory edema, hemorrhage, supramammary lymphadenopathy, and yellow serous infiltrate.
- Emphasize the proper completion of forms in both training and correlation. Provide examples of completed forms.

HACCP/Enforcement

Suggested FO recommendations:

- As the Agency works to develop and implement final policy for residues in a HACCP environment, clarification of Agency and industry roles should be emphasized.

Emphasize that it is the responsibility of industry to prevent residue violative cattle from entering the edible channel. Emphasize the Agency's responsibility to uniformly apply all regulations, policies and procedures to ensure the appropriate cattle are tested, including those condemned for pathology, verifying the efficacy of the plant's measures to eliminate potentially violative cattle from the food supply.

- Once this policy is defined, the Agency should convey it in a letter to all plants at high risk for residues. The Agency should also consider meeting with such plants to discuss residues.
- FO should work with OPPDE to provide QAs to the field. Include an example NR and workshop that demonstrates current expectations for inspection personnel and industry.
- Ensure residues are considered as part of the IDV process in slaughter establishments.

Suggested Agency Recommendations:

- ❖ Hold the planned public meeting to further explore and define residues in a HACCP environment.
- ❖ Once determinations are made and policy is formulated, provide detailed field instructions regarding verification and enforcement responsibilities.
- ❖ Consider residues and approaches to residues under HACCP as part of "HACCP Phase II".
- Consider shifting responsibility for the identification of carcasses with mastitis to industry. In the majority of establishments it was determined that the udders were removed prior to the point at which inspection personnel could safely inspect udders as part of the carcass.
- Questions and answers, and a workshop, would also be useful to industry personnel to better understand Agency expectations (current and future) related to residue testing.

Laboratory issues

Although this survey did not focus on laboratory issues, the turn around time to receive residue results was mentioned as a barrier to residue testing. Also, TSC personnel visited the Midwest Laboratory during the survey period. The TSC visit resulted in recommendations that should be included for discussion in the recommended "Agency Residue Summit".

Specific FO recommendations include:

- Work with the laboratory to ensure fastest turn around possible—improve communication.
- Create a video and/or CBT at the Midwestern Laboratory that demonstrates the process for completing a residue sample. Include a segment on tips for fastest turn around times. The video/CBT could become part of training and correlation.

Specific Agency recommendations include:

- ❖ Address the potential limited laboratory capacity that will become an increasingly serious problem as submissions increase from surveillance uniformity efforts. In addition to considering the increase in laboratory capacity, the Agency should consider the use of contract or state laboratories.

Field Information

The more individuals become stake-holders in the residue control system, the greater the likelihood the program will be uniformly applied. The NRP is not exclusive to veterinarians. Disposition and residue testing skills are no better than the quality of carcasses that line inspectors present for final disposition. GS-7s are an integral part of the process. In this regard, Circuit Supervisors, District Managers, Deputy District Managers, and District Epidemiologists, both veterinarian and non-veterinarian, should have appropriate training and correlation. The roles of all these individuals should also be clearly defined.

Specific FO recommendations include:

- ❖ FO should work with OPPDE to revise FSIS Notice 26-99 to a directive format. The directive should include a CD with colored photographs of each condition described in the directive. The directive should include discussion on risk prioritization (acute and active as highest priority for residue testing). The directive should become the focus for Agency training, materials developed for GS-7 training/correlation, and the pathology/residue correlations.
- ❖ Ensure open cases are available to field personnel (prioritize higher risk repeat violators).
- ❖ Clarify all roles in the NRP and publish in an FSIS Notice.
- ❖ Add a component to the Domestic Review Program to review residues.
- ❖ Have Circuit Supervisors review residue records as part of plant review. They could assess numbers of animals tested, reason codes for animals tested, etc. This could be covered in the Circuit Supervisor Correlation.
- Institute a rapid feedback system from TSC to inform inspectors when unacceptable paperwork is received. It could be simply an electronic post card with a checklist.

Specific Agency recommendations include:

- ❖ If/when the Agency posts the repeat violator list, issue an FSIS Notice so FSIS inspection personnel are aware and have addresses.
- Provide read-only access to RVIS at the in-plant level.
- OPPDE could create an FSIS Notice clearly defining the essential requirements for completion of FSIS Form 6600-7. A similar document from Midwestern Lab covering FSIS Form 10,000-2 would also be useful. These Notices could point out commonly-made errors and emphasize essential entries. They could be posted in inspection offices.

- A reference CD describing essential elements of residue paperwork. It could be part of the CBT for the FAST and/or could be included in a module covering all residue-related paperwork including random monitoring samples.
- A rapid feedback system from Data Services to inform inspectors when unacceptable paperwork is received. It could be simply an electronic post card with a checklist.

In-Plant Procedures

Keeping a good working incubator with a dependable security is fundamental to achieving and assuring reliable results. The present security practices of drilling holes and installing locks as well as metal bars may not be practical in all cases. There may be some other devices and means available to assure security without damaging the incubator.

Specific FO recommendations:

- ❖ Incubator problems should be addressed to the Slaughter Operations Staff.
- ❖ Ensure inspection personnel enforce 9 CFR 310.1, which requires the IIC to slow line speeds as necessary to make dispositions. The disposition should include residue testing of high risk animals. If there is limited space for the retention of these carcasses, then the line should be slowed/stopped as appropriate.
- Use pressure sensitive adhesive tape on incubator door and walls as a means of security. A break in tape may indicate tampering with the incubator.
- Build a perforated separate cabinet for incubator storage along with an electric outlet. Such a cabinet will assure air flow as well as prevent tampering with the electric plug.
- When the test is done during working hours, provide a means to lock the inspection office with a government-provided lock.
- Periodically calibrate incubator thermometers. Develop a system to distribute TempTales to all establishments for this purpose. Each VMO should maintain a history of retest due to lack of any growth. This may indicate something is wrong with the incubator.
- Clarify to the field alternate methods of retaining carcasses if cage is not large enough

Chapter VI
SURVEY RECOMMENDATIONS:
ACTION PLAN

1. Immediately:

Staffing

WHAT	WHO	HOW	WHEN
Continue general recruiting/retention efforts to fill vacant positions	Agency		Ongoing

Training

WHAT	WHO	HOW	WHEN
Add residues to the Basic Livestock Slaughter Course	HRDS		Completed
Increase time for residues in the VMO Livestock Slaughter Course	HRDS		Completed
Include Circuit Supervisors in residue correlations	TSC		FY 2001
Provide residue correlation to State personnel	TSC		FY 2001
Provide digital camera to each District Office for on-line correlation	Agency		Completed

HACCP Enforcement

WHAT	WHO	HOW	WHEN
Consider residues as part of slaughter In-Depth-Reviews (IDVs)	TSC		Ongoing

In-plant Procedures

WHAT	WHO	HOW	WHEN
Develop an Incubator Maintenance Program	TSC - OPHS		FY 2001 and beyond (Currently in process of sending out 300 new incubators)

2: Within a relatively short time frame:

General

WHAT	WHO	HOW	WHEN
Hold a Residue "Summit" meeting	FO, OPPDE, OPHS OPPDE will take lead	Meet primarily to clarify roles for all Agency program areas	ASAP

Staffing

WHAT	WHO	HOW	WHEN
Clarify role of VMO/inspection for residue tasks	FO, OPPDE	DM meeting Notice	FY 2001

Training

WHAT	WHO	HOW	WHEN
Review objectives and materials for residues in training courses	TSC-HRDS	Joint review to ensure consistent message - update as appropriate	Complete by January 2001
Provide an On-line Case of the Month on TSC web site	TSC		Begin by March 2001
Develop a video with FDA showing how they follow up with FSIS on residue cases	TSC/HRDS/FDA		By January 2001
Provide mini residue correlation at State Directors Meeting	FO - TSC		February 2001

Include information on mastitis in training materials	TSC-HRDS		FY 2001
Provide examples of completed forms	TSC		FY 2001

HACCP Enforcement

WHAT	WHO	HOW	WHEN
Develop and implement formal policy for residues in HACCP	OPPDE develop FO implement	Public Meeting - Directives	ASAP
Send letter addressing residues in HACCP to high risk plants	Agency		After the public meeting
Consider meeting with high risk plants to discuss residues	Agency		After the public meeting
Develop Q&As and examples of Noncompliance Records	OPPDE - FO		FY 2001

Laboratory Issues

WHAT	WHO	HOW	WHEN
Improve communications by utilizing electronic transmission	TSC-Lab		Ongoing
Develop video on submitting samples	TSC-HRDS-Lab		FY 2001
Remedy problem of limited lab capacity	Agency	Summit	Discuss at Summit

Field Implementation

WHAT	WHO	HOW	WHEN
Issue Directive with CD that describes conditions, includes color pictures, and prioritizes highest risks for residues	OPPDE - TSC		ASAP

Provide Open Cases directly to field	TSC	Outlook folders	FY 2001
Clarify all roles related to residues	OPPDE (after Agency summit)	FSIS Notice	By March 2001
Provide feedback on incomplete or inaccurate paperwork submitted to the TSC	TSC	Electronic post cards	By March 2001
Issue notice informing field about repeat violator list	OPPDE	FSIS Notice	Once decision final
Provide read-only access to RVIS at plant level	TSC		FY 2001
Issue FSIS Notice on completion of forms	OPPDE	FSIS Notice	FY 2001
Reference CD on completion of Forms	TSC		FY 2001
Instruct CS to review in-plant paperwork to assess level of testing, reasons for testing (could include a section in CS correlation on the how to)	CS		FY 2001
Provide rapid feedback on incomplete or incorrect paperwork sent to Data Services	Data Services	Electronic Post Card	FY 2001

In-plant Procedures

WHAT	WHO	HOW	WHEN
Address security of incubators	CS	As part of plant visits	FY 2001
Ensure §310.1 is enforced regarding slowing line speeds when necessary to make dispositions	CS - IIC		ASAP

Clarify alternate retention methods if retain cage is not large enough	OPPDE		ASAP
--	-------	--	------

3. In the longer term:

Staffing

WHAT	WHO	HOW	WHEN
Restructure VMO work to allow more time for public health/food safety work	FO - Agency	Suggested examples include a Supervisory Food Inspector for supervision and administrative functions, rotational GS-7 positions	ASAP
Update career ladder regarding residue responsibilities	Agency		ASAP

HACCP Enforcement

WHAT	WHO	HOW	WHEN
Consider residues in HACCP Phase II	Agency		
Shift responsibility for identification of mastitis to industry	Agency	As part of public process	

Field Implementation

WHAT	WHO	HOW	WHEN
Add residues to domestic reviews	TSC		ASAP

APPENDICES

Project Team List

Data Collection Instruments:

- VMO Survey
- Equipment Checklist
- Supplies Checklist
- FAST Procedure Checklist
- Observation of High Risk Carcass Selection Checklist
- Records Review
- District Managers Survey

Copies of Forms:

- Laboratory Report Form
- FAST Worksheet
- STOP Worksheet
- Noncompliance Record

Plant Awareness Package:

- FSIS Notices 26-99
- Residue Information Sheet

FSIS Notices:

- FSIS Notice 24-00
- FSIS Notice 45-99

PROJECT TEAM

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**NATIONAL RESIDUE PROGRAM
UNIFORM APPLICATION IN CULL COW PLANTS**

VMO SURVEY—DGI #1

PLANT PROFILE INFORMATION:

1. Establishment code _____ 2. Date of Visit _____

Data Collectors: 3. _____

4. _____

5. How many shifts in this plant? _____

6. What is the average daily slaughter rate? _____

7. What percentage of high risk animals are slaughtered per day? _____

8. What is the average percent of dairy cows slaughtered? _____

9. What is the average percent of beef cows slaughtered? _____

10. Does the establishment slaughter any feedlot culls? YES NO

11. How many FAST tests per day do you perform? _____

a. Do you have adequate facilities, supplies and equipment to conduct FAST tests? YES NO

12. What percent of carcasses are retained for veterinary disposition (including those for residue testing)? _____

13. How many downer animals has this establishment received in the last 30 days? *{Data Collectors: Please check the appropriate category below}*

a. _____ Establishment does not accept downer animals

b. _____ None

c. _____ 1-5

d. _____ 6-10

e. _____ 11 or more

14. Does the establishment have and use the appropriate equipment to move downer animals without dragging them? YES NO

Establishment Code _____

VMO Survey

15. Have FSIS personnel at this establishment viewed the "For the Welfare of Livestock" CD-ROM?

- | | | | | |
|---------------|-----|----|--------------|------------|
| a. VMO | YES | NO | | |
| b. Inspectors | YES | NO | Some of them | Don't Know |

16. Are FSIS personnel at this plant familiar with Temple Grandin's vocalization criteria, listed below, for evaluating humane handling of livestock?

- | | | | | |
|------------------------------|-----|----|--------------|------------|
| a. Vocalization response | YES | NO | Some of them | Don't Know |
| b. Slips and falls | YES | NO | Some of them | Don't Know |
| c. Electrical Prod Use | YES | NO | Some of them | Don't Know |
| d. Stunning efficacy | YES | NO | Some of them | Don't Know |
| e. Bleed Rail Insensibility | YES | NO | Some of them | Don't Know |
| f. Comments about the above: | | | | |

17. Number of assigned positions?

- a. VMO's _____
- b. Inspectors _____

18. Number of filled positions?

- a. VMO's _____
- b. Inspectors _____

19. Do you currently have access to Outlook? YES NO

TSC CONTACT:

20. Have you ever contacted the TSC for residue information? YES NO

{If no, go to question 18.}

If yes, what method did you use?

- | | | |
|-------------------|-----|----|
| a. Telephone | YES | NO |
| b. E-Mail | YES | NO |
| c. Fax | YES | NO |
| d. Personal Visit | YES | NO |

21. Did you have any difficulty accessing TSC personnel? YES NO

a. If yes, please describe here.

b. Did you receive a prompt response? YES NO

Establishment Code _____

VMO Survey

22. On a scale of 1 to 10, how would you rank your interaction with the TSC?
(With 1 being not satisfied, and 10 being very satisfied.) _____

a. {NOTE TO DATA COLLECTORS: If you get a response of 1, 2 or 3, please ask for and record an explanation here.}

LAB RESULTS:

23. How quickly do you receive lab results from the time of sample submission?

- a. Under 2 weeks _____
- b. 2-4 weeks _____
- c. Greater than 4 weeks _____
- d. Comments:

ROADBLOCKS:

24. Do any of the following barriers interfere with your performance of residue testing?

- a. Staffing YES NO SOMETIMES
 - (1) Is this establishment fully staffed? YES NO
 - (2) If No, please describe the number of vacancies _____
 - (3) If No, please describe what actions have been taken to fill the vacancies:

- b. Rotation YES NO SOMETIMES
- c. VMO training not adequate YES NO SOMETIMES
- d. Inspector training not adequate YES NO SOMETIMES
- e. Equipment not available YES NO SOMETIMES
- f. Equipment not functioning YES NO SOMETIMES
- g. Inadequate space YES NO
- h. Supplies not available YES NO SOMETIMES
- i. Supplies out of date YES NO SOMETIMES
- j. Supplies not in useable condition YES NO SOMETIMES
- k. Unable to secure samples YES NO SOMETIMES
- l. Unable to secure retained carcasses YES NO SOMETIMES

Establishment Code _____
 VMO Survey

- | | | | |
|--|-----|----|-----------|
| 24.m. Environmental effects on the test | YES | NO | SOMETIMES |
| (1) If yes, please explain | | | |
| n. Task interference (Other Duties) | YES | NO | SOMETIMES |
| (1) If yes, please explain | | | |
| o. Prioritization of tasks | YES | NO | SOMETIMES |
| p. Frustration with the program | YES | NO | SOMETIMES |
| (1) Carcasses condemned for other reasons | YES | NO | SOMETIMES |
| (2) We never know what happens after the test | YES | NO | SOMETIMES |
| (3) Lab is slow | YES | NO | SOMETIMES |
| (4) Communication in general | YES | NO | SOMETIMES |
| (5) Repercussions/threats/harassment by establishment | YES | NO | SOMETIMES |
| (6) Lack of support from supervisors | YES | NO | SOMETIMES |
| (7) Lack of cooperation from establishment (misinformation or lack of information about producers) | YES | NO | SOMETIMES |
| (8) Too much work | YES | NO | SOMETIMES |
| (9) Lack of communication on follow-up cases | YES | NO | SOMETIMES |
| (10) High Volume of FSIS 26-99 animals | YES | NO | SOMETIMES |
| (11) FDA does not effectively prosecute violators | YES | NO | SOMETIMES |
| q. Documenting NRs | YES | NO | SOMETIMES |
| (1) Don't know how to use electronic NRs | YES | NO | |
| r. Are there any other barriers? | YES | NO | |
| (1) If yes, please explain what they are. | | | |

GENERAL

25. Did the establishment include residues in their hazard analysis? YES NO
26. Does the establishment address residues in their HACCP plan? YES NO
27. What in-plant test(s) do you use?
- a. FAST
 - b. STOP

Establishment Code _____

VMO Survey

28. How would you prioritize these very important tasks? (With 1 being the most important—*Emphasize there is NO correct answer.*)

- a. *Salmonella* testing _____
- b. Inspector breaks _____
- c. HACCP procedures _____
- d. Pathology dispositions _____
- e. Residues _____
- f. Working the line _____
- g. SSOP _____
- h. Carcass AQL _____
- i. Offal checks _____
- j. Generic *E. Coli* checks _____
- k. Verifying humane handling/slaughter _____

29. Is the establishment cooperative in providing traceback information? YES NO

30. What is the establishment's capacity to retain carcasses?

31. Describe the criteria you use to select carcasses for residue testing at ante-mortem inspection.

32. Describe the criteria you use to select carcasses for residue testing at post-mortem inspection. *{Note to Data Collectors: If they answer that they use FSIS Notice 26-99, probe for details.}*

33. What recommendations do you have for improving residue testing in your plant?

Establishment Code _____

VMO Survey

34. Do you utilize inspection or plant personnel to assist with residue testing? YES NO

If yes, list the job title of the person utilized for each of the activities below that apply.

- a. Carcass selection for residue testing _____
- b. Sample collection _____
- c. Setting up the test _____
- d. Reading the test _____
- e. Security of samples _____
- f. Disposition of carcasses _____
- g. Ante-mortem animals selected for residue testing _____

35. How much time, on an average day, do you spend doing all aspects of residue testing? (Please record in hours/minutes) _____

36. Is the establishment doing any of their own residue sampling? YES NO
a. If yes, please describe.

37. Describe your training on conducting in-plant residue testing:

- a. OJT
- b. College Station courses (HRDS)
- c. Video
- d. Self-instructional guide
- e. CBT
- f. TSC Pathology/Residue Correlation
- g. Other (Please describe)

38. Describe the training other inspection personnel assigned to this establishment have received on in-plant residue testing.

39. Describe your Agency training on pathology:

- a. OJT
- b. College Station courses (HRDS)
- c. Pathology correlations
- d. CBT
- e. Video

Establishment Code _____
VMO Survey

39. f. Other (Please describe)

40. If you have questions on pathology, do you submit samples for histopath to the lab? YES NO

41. Do you receive a copy of the RVIS active case list from the district office:

- a. Monthly? YES NO
- b. Quarterly? YES NO
- c. Other? YES NO

(1) Describe how often _____

42. Do you get information related to residue violators from other districts? YES NO

a. If yes, please describe how.

43. What do you do if you do not have all necessary supplies to complete your residue tests?

44. Are you consistently able to obtain supplies when you order them? YES NO

a. If no, please describe the situation.

45. Do you have a copy of FSIS Notice 26-99? YES NO

46. Are the line inspectors assigned at this establishment identifying injection lesions in the following locations?

- a. neck YES NO
- b. flank YES NO
- c. axillary YES NO
- d. intra uterine YES NO
- e. perineal YES NO

Establishment Code _____

VMO Survey

- 46. f. Thoracic area YES NO
- g. Rear quarter YES NO
- h. Subcutaneous abdominal vein YES NO
- i. Other YES NO
- (1) Please describe.

47. Do plant personnel identify bolus during rumen harvest and notify inspection personnel? YES NO

48. Do you mail FSIS Form 6600-7 to the Data Center and the Technical Service Center? YES NO

49. a. if yes, at what frequency:
- (1) As completed _____
 - (2) Weekly _____
 - (3) Monthly _____
 - (4) Other (Please describe)

PROCEDURAL

50. What reference(s) do you use for performing your in-plant residue test(s)?

- a. None _____
- b. FAST guide (color copy) _____
- c. FAST guide (black and white copy) _____
- d. FAST video _____
- e. TSC _____
- f. CBT _____
- g. Other (Please describe) _____

51. What is your strategy for dealing with days in which you have a large volume of residue samples? *{Note to data collector: Please indicate all mentioned}*

- a. Don't run them _____
- b. Run a small number _____
- c. Store samples for later _____
- d. Delegate responsibility to inspection personnel _____
- e. Delegate responsibility to plant personnel _____

Establishment Code _____

VMO Survey

- 51. f. Take sample to a neighboring plant _____
- g. Ensure all residue testing is accomplished _____
- h. Other (Please describe) _____

52. Please describe all steps you follow in performing your residue test(s) from the point you have retained a carcass until the results are read.

{Note to Data Collectors: Indicate which of the below steps are described to you. If any are not mentioned, probe to see if they would be included as well.}

- a. Retain carcass _____
- b. Collect trace back information _____
- c. Collect and identify tissue samples _____
- d. Record initial data on report form _____
- e. Prepare tissue swabs *{Note for Data Collectors: Please probe for and record length of time!}* _____
- f. Streak the plate _____
- g. Identification of plate _____
- h. Placement of N5 disk *{Note to Data Collectors: Please probe for and record where it is placed}* _____
- i. Incubate plates *{Note to Data Collectors: Please probe for and record for how long}* _____
- j. Verify growth of test organism _____
- k. Verify presence of N5 zone of inhibition _____
- l. Presence/absence of zone of inhibition around swabs _____
- m. Interpret and record test results _____
- n. Release carcass if results are negative _____
- o. Submit samples to lab if results are positive _____
- p. Complete and distribute the report form _____

53. Have you experienced any problems related to the FAST test not working as expected? (Please describe)

54. Have you ever correlated with inspection personnel on residue-associated gross pathology? YES NO

- a. If Yes, please describe:

Establishment Code _____
VMO Survey

55. Do you conduct residue testing on carcasses that have been condemned for septicemia, toxemia, pyemia, pneumonia, mastitis, pericarditis, and peritonitis?
YES NO Sometimes

a. If Sometimes, please describe:

56. What do you do if you have invalid test results for the day?

57. Did you receive the updated HACCP training packet? YES NO

58. Is there any other information you want to provide regarding in-plant residue testing?

59. Additional data collector comments

NATIONAL RESIDUE PROGRAM UNIFORM APPLICATION IN CULL COW PLANTS

EQUIPMENT CHECKLIST—DGI #2

Establishment code _____

{NOTE TO DATA COLLECTORS: Please collect the information below for all incubators and their thermometers used in this plant.}

1. Incubators

	#1		#2		#3		#4
a. Make	_____		_____		_____		_____
b. Model	_____		_____		_____		_____
c. How old is it?	_____		_____		_____		_____
d. In good Repair?	YES	NO	YES	NO	YES	NO	YES NO
e. Where Located?	_____		_____		_____		_____
f. Is it secure?	YES	NO	YES	NO	YES	NO	YES NO
g. Temperature at time test was performed on the day of the visit?	_____		_____		_____		_____

2. Thermometers

	#1		#2		#3		#4
a. Type	_____		_____		_____		_____
b. Calibration	_____		_____		_____		_____
(1) Last Calibrated	_____		_____		_____		_____
(2) Frequency of Calibration	_____		_____		_____		_____
(3) How Calibrated	_____		_____		_____		_____
(4) Who Calibrated	_____		_____		_____		_____

3. Any other comments from the data collector?

NATIONAL RESIDUE PROGRAM UNIFORM APPLICATION IN CULL COW PLANTS

SUPPLIES CHECKLIST—DGI #3

Establishment code _____

1. Are the following available on the day of the visit?

- | | | |
|---------------------------------|-----|-------|
| a. Clean knife | YES | NO |
| b. Plastic bags | YES | NO |
| c. Fine tipped permanent marker | YES | NO |
| d. Rubber bands | YES | NO |
| e. U.S. Retain tags | YES | NO |
| f. Sterile cotton swabs | YES | NO |
| g. FAST Agar Plates | YES | NO |
| (1) List Expiration Date | | _____ |
| h. Spore Suspension | YES | NO |
| (1) List Manufacturer Date | | _____ |
| i. N5 Disks | YES | NO |
| (1) Note Dispenser Type | | _____ |
| j. Thumb Forceps | YES | NO |
| k. Metric Measuring Device | YES | NO |
| l. FSIS Form 6600-7 | YES | NO |
| m. FSIS Form 10000-2 (May Need) | YES | NO |

2. Data Collector comments.

NATIONAL RESIDUE PROGRAM UNIFORM APPLICATION IN CULL COW PLANTS

FAST PROCEDURE CHECKLIST—DGI #4

Establishment code _____

- | | | | |
|---|-----|----|-----|
| 1. Retain carcass | YES | NO | |
| 2. Collect traceback information—did they collect everything available (e.g. back tag, tattoo number, ear tag, any other ID)? | YES | NO | |
| 3. Collect and identify tissue samples | YES | NO | |
| 4. Record initial data on report form | YES | NO | |
| 5. Prepare tissue swabs | YES | NO | |
| a. How long does tissue sit prior to preparing test? _____ | | | |
| b. If multiple carcasses are tested, are the kidneys commingled? | YES | NO | N/A |
| c. What part of the kidney was the swab inserted into? _____ | | | |
| d. Is the tissue macerated? | YES | NO | |
| e. How long is swab kept in the tissue? _____ | | | |
| 6. Streak the plate | YES | NO | |
| 7. Identification of plate | YES | NO | |
| 8. Placement of N5 disk | YES | NO | |
| a. Where is it placed? _____ | | | |

Establishment code _____
FAST Procedure Checklist

- | | | |
|--|-----|----|
| 9. Incubate plates | YES | NO |
| a. How long? _____ | | |
| b. If multiple plants, how was the incubator loaded? | | |
| c. What was the temperature of the incubator during loading? _____ | | |
| 10. Verify growth of test organism | YES | NO |
| 11. Verify presence of N5 zone of inhibition | YES | NO |
| 12. Presence/absence of zone of inhibition surrounding swabs | YES | NO |
| a. What technique was used to measure zone of inhibition? | | |
| 13. Interpret and record test results | YES | NO |
| 14. Release carcass if results are negative | YES | NO |
| 15. Submit samples to lab if results are positive | YES | NO |
| a. How was the sample prepared and submitted to the lab? | | |
| 16. Complete and distribute the report form | YES | NO |
| 17. Data Collector comments. | | |

NATIONAL RESIDUE PROGRAM UNIFORM APPLICATION IN CULL COW PLANTS

OBSERVATION OF HIGH RISK CARCASS SELECTION CHECKLIST— DGI #5

Establishment code _____

1. Please refer to FSIS 26-99 for descriptions of the following pathologies and conditions. Put a checkmark under VMO if the VMO observed the condition and performed an in-plant residue test. Put a checkmark under Data Collector if you observed the condition and would consider it appropriate to test as per FSIS Notice 26-99. *{Note: You may end up with a checkmark in one column and not the other, checkmarks in both columns, or checkmarks in neither.}* Please note any discrepancies in the space for comments.

	<u>VMO</u>	<u>Data Collector</u>
<u>Ante mortem:</u>		
a. Injection sites	_____	_____
(1) Comments:		
b. Downers	_____	_____
(1) Comments		
c. Residue Suspects	_____	_____
(1) Suspects with signs of acute or generalized conditions	_____	_____
(2) Cows with evidence of surgery	_____	_____
(3) Slow, dull, dehydrated and depressed cows	_____	_____
(4) Comments		
<u>Post Mortem:</u>		
d. Mastitis	_____	_____
(1) Comments		

Establishment code _____

Observation of High Risk Carcass Selection Checklist

	<u>VMO</u>	<u>Data Collector</u>
e. Metritis (1) Comments	_____	_____
f. Peritonitis and Surgery (1) Comments	_____	_____
g. Injection sites (1) Comments	_____	_____
h. Pneumonia (1) Comments	_____	_____
i. Pericarditis (1) Comments	_____	_____
j. Endocarditis (1) Comments	_____	_____
k. Abomasal Disease (1) Comments	_____	_____
l. Septicemia and Pyemia (1) Comments	_____	_____
m. Acute Cellulitis/Other Acute Inflammations _____ (1) Comments	_____	_____

**NATIONAL RESIDUE PROGRAM
UNIFORM APPLICATION IN CULL COW PLANTS**

RECORDS REVIEW—DGI #6

Establishment code _____

1. How many Noncompliance Reports (NR's) for humane handling violations has this establishment received in the past 12 months? _____

- a. What, if any, deficiencies were documented?
 - (1) Facilities:
 - (2) Handling:
 - (3) Stunning:

(Data Collectors: Randomly select a minimum of three of each type of record listed below)

2. FSIS Form 10,000-2:

- a. Is a copy retained in the plant? YES NO
- b. Are they completely filled out? YES NO
 - (1) If no, what is missing?
- c. Are they properly filled out? YES NO
 - (1) If no, please explain

Prompts for data collector:

Look for in-plant test type

Species – beef or dairy

Tissue type—is it accurately annotated?

Establishment code _____
Records Review

3. FSIS Form 6600-7:

- a. Are they complete? YES NO
(1) If no, what is missing?
- b. Are they properly filled out? YES NO
(1) If no, please explain

Prompts for data collector:

*Is the complete retain tag number documented?
Is the back tag number completely documented?*

4. Residue Violation Noncompliance Records:

- | | NR#1 | NR#2 | NR#3 |
|---|-------|-------|-------|
| a. What procedure codes were used? | _____ | _____ | _____ |
| b. What trend indicators were used? | _____ | _____ | _____ |
| c. Did the establishment response meet the requirements of 417.3? | Y N | Y N | Y N |

If no, ask VMO whether the establishment documented corrective actions on other records (HACCP record, memos or letters from establishment attached to the NR), and record the answers below:

(1) NR#1 _____

(2) NR#2 _____

(3) NR#3 _____

5. Additional Data Collector comments.

**NATIONAL RESIDUE PROGRAM
UNIFORM APPLICATION IN COW CULL PLANTS**

DISTRICT MANAGERS SURVEY—DGI #7
{Selected from those districts in which the selected plants are located}

District name and code _____

1. Are you aware of the District Office role in the residue program? YES NO
{Data Collectors, please prompt—if necessary—for the following:}

a. Proper flow of information from TSC to field inspectors YES NO

b. Assistance in tracebacks YES NO

c. Providing training to the field staff in conducting residue testing and procedures? YES NO

d. Providing information related to open case follow-up? YES NO

e. Providing information to producers and establishments related to incoming animals for follow up testing? YES NO

f. Other *{Please describe}*

District name and code _____

District Manager Survey

2. What resources do you utilize for residue information? *{Data Collectors, please prompt—if necessary—for the following:}*

- | | | |
|-----------------------------------|-----|----|
| a. TSC | YES | NO |
| b. Training Center (HRDS) | YES | NO |
| c. Epidemiologists | YES | NO |
| d. OPPDE | YES | NO |
| e. OPHS | YES | NO |
| f. Field Operations HQ | YES | NO |
| g. Compliance | YES | NO |
| h. Other <i>{Please describe}</i> | | |

3. Who is the primary person responsible for residue work in your district (by title—no name)?

4. Is there anything the TSC can do that will facilitate your role related to residues?

5. What suggestions do you have for the Agency for improvement of uniform implementation of FSIS Notice 26-99?